

Evaluation Tests to Consider - ISO 10993-1:2003*

Section 6: Selection of biological evaluation tests; Tables 1 / 2

Device Categorized as:		Biological Effects											
Body Contact		Contact Duration	Cytotoxicity	Sensitization	Irritation or Intracutaneous Reactivity	Systemic Toxicity (acute)	Subacute and Subchronic Toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronic Toxicity	Carcinogenicity	
		Limited •Less than 24 hours Prolonged •24 hours to 30 days Permanent •Over 30 days											
Surface Device	Skin	Limited	♦	♦	♦								
		Prolonged	♦	♦	♦								
		Permanent	♦	♦	♦								
	Mucosal Membrane	Limited	♦	♦	♦								
		Prolonged	♦	♦	♦								
		Permanent	♦	♦	♦		♦	♦					
	Breached or compromised surfaces	Limited	♦	♦	♦								
		Prolonged	♦	♦	♦								
		Permanent	♦	♦	♦		♦	♦					
External communicating device	Blood Path, Indirect	Limited	♦	♦	♦	♦				♦			
		Prolonged	♦	♦	♦	♦				♦			
		Permanent	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	
	Tissue/Bone/Dentin	Limited	♦	♦	♦								
		Prolonged	♦	♦	♦	♦	♦	♦	♦				
		Permanent	♦	♦	♦	♦	♦	♦	♦		♦	♦	
	Circulating Blood	Limited	♦	♦	♦	♦					♦		
		Prolonged	♦	♦	♦	♦	♦	♦	♦	♦	♦		
		Permanent	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦
Implant device	Tissue/Bone	Limited	♦	♦	♦								
		Prolonged	♦	♦	♦	♦	♦	♦	♦				
		Permanent	♦	♦	♦	♦	♦	♦	♦				
	Blood	Limited	♦	♦	♦	♦	♦			♦	♦		
		Prolonged	♦	♦	♦	♦	♦	♦	♦	♦	♦		
		Permanent	♦	♦	♦	♦	♦	♦	♦	♦	♦	♦	

*Additional tests may be required to satisfy FDA requirements.